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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,721	06/25/2001	James S. Huston	P 23,611-A USA	2094

7590 12/16/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/888,721

Applicant(s)

HUSTON ET AL.

Examin r

Christopher H Yaen

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 20.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Upon further review and reconsideration to the arguments filed 9/24/2003, the previous restriction requirement is vacated in light of a new restriction requirement, hereto.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-9,13, 16-29, and 52 drawn to a gene delivery compound comprising a single chain binding polypeptide, a nucleic acid binding moiety, and a nucleic acid binding effector segment classified in class 530, subclass 387.3.
 - II. Claims 1-8, 10,14, 16-29, and 52 drawn to gene delivery compound comprising a single chain binding polypeptide, a nucleic acid binding moiety, and an effector segment that facilitates endosomal escape or avoidance, classified in class 530, subclass 402.
 - III. Claims 1-8, 11,16-29, and 52 drawn to gene delivery compound comprising a single chain binding polypeptide, a nucleic acid binding moiety, and an effector segment that facilitates non-endosomal transport, classified in class 530, subclass 388.22.
 - IV. Claims 1-8, 12, 15,16-29, and 52 drawn to gene delivery compound comprising a single chain binding polypeptide, a nucleic acid binding moiety, and an effector segment that facilitates entry into the nucleus of a target cell, classified in class 530, subclass 388.26.

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- V. Claims 30-41, 42,46, and 49-51, drawn to a gene delivery compound comprising a single chain binding polypeptide, a lipid-associating moiety, and an effector segment that is capable of associating with a nucleic acid classified in class 424, subclass 182.1.
- VI. Claims 30-41, 43,47, and 49-51, drawn to a gene delivery compound comprising a single chain binding polypeptide, a lipid-associating moiety, and an effector segment that facilitates endosomal escape, classified in class 530, subclass 402.
- VII. Claims 30-41, 44, and 49-51, drawn to a gene delivery compound comprising a single chain binding polypeptide, a lipid-associating moiety, and an effector segment that facilitates non-endosomal transport, classified in class 530, subclass 388.22.
- VIII. Claims 30-41, 45, 48, and 49-51, drawn to a gene delivery compound comprising a single chain binding polypeptide, a lipid-associating moiety, and an effector segment that facilitates entry into the nucleus, classified in class 530, subclass 388.26.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because the gene delivery vehicles differ in their structural components. The eight groups are divided into

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two distinct sets of compounds, (a) those that binds to and have nucleic acid binding moieties, and (b) those that bind to and have lipid-associating moieties. Those compounds belong to (a) and (b) further differ one from the other because the delivery vehicles have different effector segments that help in the localization to different parts of the cell, which would have different structural requirements. Thus, the inventions are distinct and differ not only because they have different structures, but also because they are used for localization of the gene-delivery vehicle to different parts of the cell.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. If applicant elects any one of groups I-IV for prosecution on the merits, applicant must select **one species from each of the following groups**:

- i. marker: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor, Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1;
- ii. nucleic acid binding moiety: salmon protamine, subfragment of salmon protamine, human histone H1, subfragment of human histone H1, human protamine, subfragment of human protamine, HMG, or polylysine;

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- iii. therapeutic gene: lymphokine, tumor necrosis factor, intrabody, tumor suppressor genes, p53, proapoptotic genes, suicide genes, prodrug converting genes, HSV-TK, or anti-angiogenic genes; and
 - iv. conjugate: C6ML3-9 sFv'-H1, C6ML3-9 sFv'-P1 or C6ML3-9 sFv'-SP.
- b. If applicant elects any one of groups V-VIII for prosecution on the merits, applicant must select **one species from each of the following groups:**
- i. marker from: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor, Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1; and
 - ii. lipid associating compound from: linear, branched, cyclic, or polycyclic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6,7,26-29,35, and 36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Gene Yao on December 10, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen

Christopher Yaen
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December 15, 2003